



Maine Department of Environmental Protection

Department Rule Chapter 885

*Designation of Formaldehyde as a Priority Chemical and
Regulation of Formaldehyde in Children's Products*

Basis Statement

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INTRODUCTION

The objective of Maine's law, *Toxic Chemicals in Children's Products*, 38 M.R.S.A. §§1691 - 1699-B, is to reduce exposure of children and other vulnerable populations to chemicals of high concern by substitution of safer alternatives when feasible, as set forth in the Legislature's Declaration of Policy at 38 M.R.S.A. §1692. To accomplish this, the law provides the Maine Department of Environmental Protection ("Department") the regulatory authority to collect information on chemical use and, if applicable, prohibit the sale of children's products containing priority chemicals when safer alternatives are available.

The law requires that a substance meet certain criteria to be designated a priority chemical, and that the Department provide its findings in support of such a designation. This document sets forth such findings of fact supporting the designation of formaldehyde as a priority chemical, and is intended to serve as the Basis Statement for the designating rule, Chapter 885 *Designation of Formaldehyde as a Priority Chemical and Regulation of Formaldehyde in Children's Products*. Department rule Chapter 880, *Regulation of Chemical Use in Children's Products*, establishes routine technical rulemaking as the process by which the Department will designate priority chemicals.

Widely used in consumer products, formaldehyde functions as a preservative and biocide, provides textile wrinkle resistance and antistatic properties, is a binding agent for pigments, and is an intermediate in the manufacture of plasticizers and resins. Therefore, the Department proposes a reporting rule for certain categories of products in order to determine where formaldehyde may be present in children's products which are sold in the State of Maine.

Through this rulemaking, the Department designates formaldehyde (registered Chemical Abstract Service number 50-00-0, as noted on Maine's Chemicals of High Concern List) as a priority chemical in accordance with 38 M.R.S.A. §1694 and establishes a reporting requirement for manufacturers offering certain children's products for sale in the State of Maine.

I. FORMALDEHYDE BACKGROUND INFORMATION

Formaldehyde is the simplest aldehyde, existing at room temperature as a nearly colorless gas with a pungent odor (ATSDR 1999, HSDB 2009). A highly reactive gas, formaldehyde is formed by oxidation or incomplete combustion of hydrocarbons (NTP 2010). Although formaldehyde is produced endogenously in humans and most life forms, it is most commonly available in commerce as 30% to 50% (by weight) aqueous solutions of the hydrated form, commonly referred to as formalin (IARC 2006). Formalin contains stabilizers; in their absence, formaldehyde solutions oxidize, forming formic acid and polymerizing to form oligomers, including paraformaldehyde (a polymer with 8 to 100 units of formaldehyde) (HSDB 2009). Although formaldehyde can exist as a solid, in the form of 1,3,5-trioxane ((CH₂O)_n) and its polymer, paraformaldehyde, this form is less frequently used in consumer products. Formaldehyde gas is generally stable in the absence of water, but is flammable and can be ignited by exposure to various types of heat sources, and reacts violently with strong oxidizing agents. (NTP 2011)

Formaldehyde's predominant use (greater than 50% of its total consumption) is in the production of industrial resins (such as urea-formaldehyde, phenol-formaldehyde, polyacetal, and melamine-formaldehyde resins). Used to manufacture numerous commercial products, such as plastics, synthetic fibers and textile finishings, formaldehyde is also used as a chemical intermediate to produce other chemicals. Approximately 5% of all commercially used formaldehyde functions as a disinfectant or antimicrobial agent, as a biocide or preservative, and has been known to be used in cosmetic products. Formaldehyde is used as an antimicrobial agent in cosmetics such as soaps, shampoos, hair preparations, deodorants, lotions, make-up, mouthwashes, and nail products (IARC 2006). Formaldehyde is registered as a materials preservative in consumer products such as detergents and general-use cleaners. (ASTDR 1999, IARC 2006, EPA 2008)

Exposure to the general population occurs primarily from breathing affected indoor or outdoor air, tobacco smoke, use of cosmetic products containing formaldehyde, and, to a more limited extent, from ingestion of food and water. The most significant sources of airborne formaldehyde exposure include combustion sources, off gassing from construction and home-furnishing products, and off gassing from consumer goods. Determinants of indoor air levels of formaldehyde include its sources, the age of source materials, temperature, humidity, and ventilation rates. (IARC 2006) The general population may also be exposed to formaldehyde by handling consumer products that contain formaldehyde as an antimicrobial agent, or from its use as a mildewcide for clothing and linens (EPA 2008).

Although formaldehyde use has declined in the current production of cosmetics, the use of formaldehyde releasers is common. Data from the U.S. Food and Drug Administration's Voluntary Cosmetic Registration Program Database indicates that nearly 20% of cosmetic products contained formaldehyde (including formalin) or any of eight formaldehyde-releasing preservatives (listed as: benzylhemiformal; 5-bromo-5-nitro-1,3-dioxane; 2-bromo-2-nitropropane-1,3-diol; diazolidinyl urea; 1,3-dioxane; 2-bromo-2-nitropropane-1,3-diol;

diazolidinyl urea; 1,3-dimethylol-5,5-dimethylhydantion; imidazolidinyl urea; quaternium-15; or sodium hydroxymethylglycinate). (NTP 2011) Other products that often contain formaldehyde and/or formaldehyde releasers include household cleaning agents, soaps, shampoos, lotions, cosmetics, mouthwash, nail care products, and paints. (WHO 2002)

Health Concerns

Strong, credible scientific evidence leading to exposure concerns include formaldehyde's classification as a *known human carcinogen* by the World Health Organization, International Agency for the Research of Cancer ("IARC") (IARC 2006) and the U.S. Department of Health and Human Services, National Toxicology Program ("NTP") (Report on Carcinogens, 12th Edition (2011)). The NTP Report on Carcinogens describes this classification as, "*Known To Be Human Carcinogen: There is sufficient evidence of carcinogenicity from studies in humans, which indicates a causal relationship between exposure to the agent, substance, or mixture, and human cancer.*" This classification represents the strongest level of confidence in a carcinogenic toxicity rating.

Additionally, in a 2004 review, the International Agency for the Research of Cancer placed formaldehyde into its highest ranking carcinogenicity classification, *carcinogenic to humans* (Group 1) (IARC Monographs Review of Human Carcinogens, Volume 100F.). This category is used when "there is *sufficient evidence of carcinogenicity in humans* ... an agent may be placed in this category when evidence of carcinogenicity in humans is less than *sufficient* but there is sufficient evidence of carcinogenicity in experimental animals and strong evidence in exposed humans that the agent acts through a relevant mechanism of carcinogenicity." (IARC Preamble 2006)

Inhalation of formaldehyde can result in irritation to the lungs, causing bronchial and pulmonary irritation, sore throat, and coughing. Irritative effects have consistently been reported after exposure to formaldehyde; these effects have been observed in children, with a wide variation in susceptibility reported. Airborne formaldehyde is known to irritate the eyes, nose and throat. Although symptoms are deemed rare at concentrations below 0.5 ppm, upper airway and eye irritation, changes in odor threshold, and neurophysiological effects (e.g. insomnia, memory loss, mood alterations, nausea, and fatigue) have been reported at concentrations ≤ 0.1 ppm. (NTP 2010) Other effects include allergic contact dermatitis, histopathological abnormalities of the nasal mucosa, reduced lung function, altered immune response, and hemotoxicity. (IARC 2006)

Typically, exposure to formaldehyde occurs through inhalation or skin contact, and effects associated with exposure happen primarily at the site of first contact. For instance, inhalation of indoor releases of formaldehyde from home products can cause nose and throat irritation and have been linked to asthmatic symptoms. In addition to inhalation concerns, absorption of formaldehyde from products, such as hand cream or suntan lotion, has been estimated at up to 0.1 mg for a typical application, assuming a rate of 5% absorption through the skin. (ATSDR 1999)

Formaldehyde is also classified as a strong sensitizer, eliciting an often alarming allergic reaction on the dermal layer after repeated contact with skin.

Other than occupational settings, the highest levels of airborne formaldehyde have been detected indoors where it is released from various building materials, consumer products, and tobacco smoke. Formaldehyde may also be present in food, either naturally or as a result of contamination. (IARC 2006)

II. Statutory Prerequisites for Priority Designation

To be included on Maine's list of Chemicals of High Concern ("CHC"), a chemical must have strong, credible scientific evidence classifying it as either a reproductive or developmental toxicant, endocrine disruptor, or human carcinogen. Formaldehyde meets this requirement after having received the highest possible rating by two of the world's leading cancer research centers (IARC 2012 and NTP 2011) as a *known* human carcinogen.

Maine law at 38 M.R.S.A. § 1694 states that the, "commissioner may designate a chemical of high concern as a priority chemical if the commissioner finds, in concurrence with the Department of Health and Human Services, Maine Center for Disease Control and Prevention:

- A. The chemical has been found through biomonitoring to be present in human blood, including umbilical cord blood, breast milk, urine or other bodily tissues or fluids;
- B. The chemical has been found through sampling and analysis to be present in household dust, indoor air or drinking water, or elsewhere in the home environment; or
- C. The chemical is present in a consumer product used or present in the home."

The statute authorizes the commissioner to designate chemicals that meet one or more of these criteria as priority chemicals by the adoption of routine technical rules. Formaldehyde meets one or more of the criteria for this designation.

A. Priority Designation Presence in the Home Environment Criteria

The Maine CDC Concurrence for Formaldehyde as a Priority Chemical document (ME-CDC 2013) describes levels of formaldehyde detected in indoor air in the home as dependent on several factors, including formaldehyde levels in ambient outdoor air, humidity, temperature, season, home structure and the home's construction materials. In 2008, the U.S. Centers for Disease Control and Prevention ("CDC") sampled 519 travel trailers, park models and manufactured homes for formaldehyde. The average formaldehyde level in the indoor air of these 519 temporary housing structures was 95 ug/m³, with levels ranging from 4 - 726 ug/m³ (CDC 2010), which provides strong evidence that formaldehyde can be present in indoor air in the home environment. (ME-CDC 2013)

B. Priority Designation Presence in Consumer Products Used or Present in the Home

Formaldehyde has been measured in a broad spectrum of consumer products ranging from children's personal care products and cosmetics, to household cleaning agents and paints (WHO 2002).

The Danish Ministry of the Environment, Environmental Protection Agency ("DEPA") conducts a consumer products research program which performs laboratory analysis on consumer products to determine presence, or the absence of, chemicals of concern. Within the DEPA's Survey of Chemical Substances in Consumer Products, No. 102 (2009), spectrophotometric analyses confirmed the presence of free formaldehyde in commonly available bed linen both before and after the items were washed. Within this same product survey, formaldehyde was also found in measurable quantities in children's jackets, mittens, and diapers. (DEPA No. 102 (2009))

During another DEPA product survey (No. 90), researchers analyzed baby products such as nursing pillows, mattresses, and baby carriers. Free formaldehyde was measured in two nursing pillows at 26 and 65 $\mu\text{g/g}$ respectively. The results of migration tests in sweat for free formaldehyde in these same two products measured amounts at 74 and 376 $\mu\text{g/g}$ respectively. (DEPA 2008)

Formaldehyde is known to be used as an antimicrobial in various cosmetic products, at reported levels of up to 0.5% in lotions, cream rinses, and bubble-bath oils, and up to 4.5% in nail hardeners. Other cosmetic products that may contain formaldehyde include suntan lotions, hand creams, bath products, eye make-up, nail creams, soaps, shampoos, hair preparations, deodorants, and mouth washes. The Agency for Toxic Substances and Disease Registry ("ATSDR") notes that trace levels of formaldehyde may exist in some cosmetic products as a result of its use as a disinfectant for the equipment used to manufacture the product. Formaldehyde has been used as a preservative in numerous consumer products, including household cleaning agents, dishwashing liquids, fabric softeners, and carpet-cleaning agents. This chemical has been confirmed present in moist toilet tissues used by parents on babies at levels exceeding 100 $\mu\text{g/g}$ (100 ppm) (WHO 2002). Formaldehyde is also known to have been added to children's paint products as a preservative and measured at levels of 441 to 793 mg/kg in two types of finger paints (Garriagos et al. 2001, NTP 2010, ME-CDC 2013).

The use of formaldehyde-based resins to produce crease-resistant fabrics began in the 1950s. The introduction of dimethyloldihydroxyethyleneurea resins in 1970 reduced the levels of free formaldehyde in fabrics to approximately 0.15%-0.2%. Since that time a gradual decrease in the use of formaldehyde in fabrics has occurred. (IARC 2006) In 1999, a follow-up study to the Inhalation Toxicology Research Institute's 1983 measurement of formaldehyde release rates for various types of consumer products was performed as a result of changes in product manufacturing processes. The resulting study (Kelly et al. 1999) concluded that the rates of formaldehyde release from permanent press fabrics ranged from 42 to 214 $\mu\text{g/m}^2/\text{h}$. In contrast, nail polish has been measured to release formaldehyde at a rate of 20,700 $\mu\text{g/m}^2/\text{h}$ (ME-CDC

2013). For a variety of bare urea-formaldehyde wood products releases ranged from 9 to 1,578 $\mu\text{g}/\text{m}^2/\text{h}$, and for coated urea-formaldehyde wood products release rates ranged from 1 to 461 $\mu\text{g}/\text{m}^2/\text{h}$ (IARC 2006).

Formaldehyde use in consumer products continues, as confirmed by the 434 reports of formaldehyde presence in children's products submitted to the Washington State Department of Ecology as of May 2015. Common products that contain formaldehyde, formalin and/or paraformaldehyde include cosmetics and personal care products which may provide exposure through various means, such as hair (shampoos and hair preparations), skin (deodorants, bath products, lotions), eyes (mascara, eye make-up), oral mucosa (mouthwashes), nails (nail creams, polishes, and lotions), and airways (aerosol products). (IARC 2006)

III. Purpose of Priority Designation

The presence of formaldehyde has been confirmed in commonly used children's products through product testing at the federal level and through required manufacturer reporting to the Washington State Department of Ecology, although limited in scope. Rather than require reporting, other states have chosen alternative strategies for formaldehyde restriction; both Massachusetts and Minnesota currently prohibit the sale of certain consumer products containing formaldehyde. The most recent, and most restrictive, is Minnesota law (Minn. Statutes § 325F.08-325F.16) which includes a prohibition on ingredients that chemically degrade, under normal conditions of temperature and pressure, to release formaldehyde. Policy at the federal level requires a warning label when greater than 1% formaldehyde is used to make products which are regulated by the federal Consumer Product Safety Commission. Having varying levels of impact, each regulation listed provides limited information. With its proposed rule, the Department seeks to gain a more comprehensive understanding of the current use of formaldehyde in children's products sold within the State of Maine, information which is not currently available through any other source.

Due to its toxicity, Maine has already designated formaldehyde as a priority toxic chemical under Maine's Toxic Use Reduction law ("TUR") (38 M.R.S.A. §§ 2321-2330). In an effort to reduce formaldehyde's use in manufacturing processes, this law provides the Department the authority to require manufacturers within the State of Maine using more than 1,000 pounds of formaldehyde in a calendar year to report its use to the Department. Technical assistance provided through the TUR program encourages industry to reduce the use of formaldehyde and encourages the use of safer alternatives. This designation through TUR provides the Department with valuable information regarding the use of formaldehyde in manufacturing processes within the State of Maine, but does not include children's products within its scope.

Designating formaldehyde as a priority chemical within the Safer Chemicals Program will require disclosure on how and where formaldehyde is intentionally added to certain categories of children's products. This information regarding the use of formaldehyde in products available to the Maine consumer will provide the Department with more details regarding formaldehyde use

than has been gleaned from any current public source, and will provide a more complete analysis than can be accomplished in the absence of such a reporting requirement.

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